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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yukio KAWASHIMA

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EXAMINER

BOSWORTH, KAMI A

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,957	Applicant(s) KAWASHIMA, YUKIO	
	Examiner KAMI A. BOSWORTH	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is responsive to the amendment filed on 5/22/2006. As directed by the amendment: the specification and abstract have been amended, claims 1-4 have been amended and claims 5 and 6 have been added. Thus, claims 1-6 are presently pending in this application.

Claim Objections

1. Claim 1 is objected to because of the following informalities: On line 8 of claim 1, it is believed that the term "a" should be inserted between the terms "exposing" and "tip end side", so that the phrase reads "exposing a tip end side". Appropriate correction is required.
2. Claims 3 and 5 are objected to because of the following informalities: On lines 1-2 of claims 3 and 5, the phrase "wherein a locking portion for locking the locking portion of the cap..." appears to be incorrect grammatically. It is suggested the claim be amended to read "further comprising a locking portion for locking the locking portion of the cap...". Appropriate correction is required.
3. Claims 4 and 6 are objected to because of the following informalities: On line 4 of claims 4 and 6, the term "locking portions of said cap" lack proper antecedent basis as only a singular locking portion has been provided for. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Giambattista et al. (PG PUB 2003/0014018).

6. Re claim 1, Giambattista et al. disclose an injection needle (best seen in Fig 12) comprising: a fitting member 140 (Fig 9, 12) fitted to a parenteral solution discharge port 144 (Fig 12) of an injector body 121 (Fig 12); a needle body 134 (Fig 9, 12) held by the fitting member; a cap 124 (Fig 9, 12) detachably attached to the fitting member to cover the needle body (as seen in Fig 12), the cap being arranged to fit the fitting member with the cap attached thereon to the injector body and to detach the cap from the fitting member (Para 52, 57); a cover member 22 (Fig 9, 12) moveable in an axial direction of said needle for (a) exposing a tip end side 138 (Fig 12) of the needle body by moving to a base end side 136 (Fig 12) of the needle body (as seen in Fig 14), and (b) covering the tip end side of the needle body by moving to the tip end side of the needle body (as seen in Fig 13); said cap including a locking portion 184 (Para 52, 57) that is lockable

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at the cover member to move the cover member to the tip end side of the needle body with the cap (Para 52, 57).

7. Re claim 2, Giambattista et al. disclose that said fitting member includes an extended portion 141 (Fig 12) extending in the axial direction toward the tip end side of the needle body (as seen in Fig 12); and said cover member having a cylindrical shape (as seen in Fig 9) and engagable with the extended portion moveable in the axial direction (as seen in Fig 13, 14; Para 50, 60).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giambattista et al. (PG PUB 2003/0014018) in view of Alchas et al. (PG PUB 2002/0045858).

10. Re claims 3 and 5, Giambattista et al. disclose a locking portion 166 (Fig 9) for locking the locking portion of the cap at a predetermined position in the axial direction of said cover member (Para 52, 57). Giambattista et al. does not disclose the locking portion of the cap being arranged to ride over the locking portion of the cover member in the axial direction by elastic deformation. Alchas et al., however, teaches a substantially similar device comprising a locking portion 74 (Fig 3A) in a cap 34 (Fig 3A)

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and a locking portion 76 (Fig 3A) in a cover member 24 (Fig 3A) wherein the locking portion of the cap being arranged to ride over the locking portion of the cover member in the axial direction by elastic deformation (Para 33) for the purpose of securing the cap to the cover member (Para 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Giambattista et al. to include attachment via elastic deformation, as taught by Alchas et al., for the purpose of securing the cap to the cover member (Para 33).

11. Re claims 4 and 6, Giambattista et al. disclose that the locking portion of the cap includes a flange projecting in a radial direction of the cover member (Para 52, 57) and the locking portions of the cover member being projectingly arranged to be spaced from each other in a circumferential direction at a plurality of spots on an inner peripheral surface of the cap (Para 52, 57) but does not disclose that the locking portion of the cover member includes a flange and the locking portions of the cap are projectingly arranged to be spaced from each other at a plurality of spots. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Giambattista et al. so that the cover member includes a flange and the cap has projectingly arranged locking portions since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767